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SECTION 7

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of Safety and Effectiveness	Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency. NEW DEVICE NAME: VICRYL (polyglactin 910) Periodontal Mesh PREDICATE DEVICE NAME: GORE-TEX^{R} Periodontal Material

510(k) SUMMARY

Device Description	VICRYL periodontal mesh is prepared from a synthetic, bioabsorbable copolymer of glycolide and lactide. The woven mesh is prepared from undyed strands identical to the strands used in VICRYL (polyglactin 910) synthetic, bioabsorbable suture. VICRYL periodontal mesh is provided sterile, available in various sizes and shapes each with synthetic, bioabsorbable VICRYL ligatures affixed to the barrier.
Intended Use	VICRYL periodontal mesh is intended for use as a barrier to provide temporary support during the early stages of the healing process following periodontal surgery.

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510(k) SUMMARY, Continued

Indications Statement	VICRYL periodontal mesh is a bioabsorbable implantable material intended to aid in the healing of periodontal defects.
Technological Characteristics	The new device provides a membrane barrier to apical migration of gingival epithelium during a period of periodontal ligament regeneration. Unlike the predicate device, the new device does not need to be removed post-implantation.
Performance Data	Analytical characterization to assess thermal properties and molecular weight was conducted. Preclinical laboratory and clinical evaluations were conducted to ensure that the device functioned as intended. Sufficient data has been gathered from preclinical and clinical testing to assess the safety and effectiveness of the new device.
Conclusions	Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug, and Cosmetic Act.
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